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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/552,340	12/12/2006	Toshihiro Yamamoto	64301 (46590)	9448

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EXAMINER	
RICCI, CRAIG D	

ART UNIT	PAPER NUMBER
1614	

MAIL DATE	DELIVERY MODE
04/14/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/552,340	YAMAMOTO ET AL.	
	Examiner	Art Unit	
	CRAIG RICCI	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-14* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/06/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without specifying traverse of the species compound and a hypolipidemic agent in the reply filed on 03/03/2009 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

2. The requirement is still deemed proper and is therefore made FINAL.

3. The elected species read upon claims 1-14.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. **Claims 1-14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

6. The term "excessive" in claim 1 is a relative term which renders the claim indefinite. The term "excessive" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. As such, instant claim 1 is indefinite because a person of ordinary skill in the art would not be reasonably appraised of the metes and bounds of an agent for inhibiting an "excessive" effect of

NAD(P)H oxidase. Since dependent claims 2-14 fail to further clarify the meaning of the term, these claims are rejected as indefinite also.

Claim Rejections - 35 USC § 102

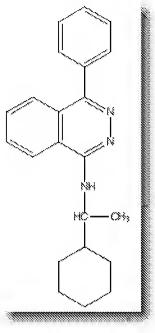
7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. **Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by *Iwase et al* (US 5,324,727).**

9. Instant claim 1 is drawn to an agent for inhibiting excessive NAD(P)H oxidase, which comprises a compound for inhibiting an excessive effect of NAD(P)H oxidase that does not substantially inhibit the effect of leukocyte NADPH oxidase but inhibits the effect of NAD(P)H oxidase in a tissue other than leukocyte. More specifically, the

following compound species is encompassed by Applicant's election:



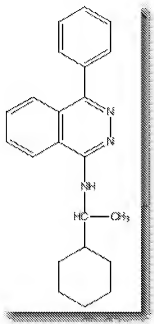
10. *Iwase et al* teach the above compound (Columns 87-88, Compound 431) as a platelet agglutination inhibitor useful as therapeutic medicine for the treatment of cerebrovascular disorders, ischemic heart disease, and circulation disorders (Column 1, Lines 9-16) which encompasses an agent/composition comprising the compound as an active agent as recited by instant claims 1, 6-7 and 13. Although *Iwase et al* do not disclose that the agent comprising the compound inhibits the effect of NAD(P)H oxidase in a tissue other than leukocyte as recited by instant claim 1, Applicant is advised that intended use limitations within product claims do not carry patentable weight unless the recitation of the intended use of the claimed invention results in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the prior art structure is

identical to the instantly claimed compound structure. As such, the agent taught by *Iwase et al* would be capable of performing the intended use recited by instant claim 1. As stated in *In re Best, Bolton, and Shaw*, "Where... the claimed and prior art products are identical or substantially identical, or are produced by identical or substantially identical processes, the PTO can require an applicant to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product" 195 USPQ 430, 433, 562 F2d 1252 (CCPA 1977). See also *In re Fitzgerald* 205 USPQ 594, 597, 619 F2d 67 (CCPA 1980): the burden is shifted to the applicants to "prove that subject matter shown to be in the prior art does not possess characteristic relied on."

11. Instant claim 2 is drawn to the agent of claim 1 wherein the tissue (in which the effect of NAD(P)H oxidase is inhibited) is a tissue of a vascular cell, the heart, the kidney, the retina, etc. Thus, claim 2 further limits the intended use limitation of instant claim 1 by defining the tissue in which the excessive effect of NAD(P)H oxidase is inhibited. Yet, as discussed above, intended use limitations in product claims are not afforded patentable weight unless the recitation of the intended use of the claimed invention results in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. Accordingly, claim 2 is rejected for the same reason as applied to instant claim 1; i.e., the prior art structure is identical to the instantly claimed compound structure. Furthermore, it is also noted that *Iwase et al* specifically teach the agent for the treatment of cerebrovascular disorders, ischemic heart disease, and circulation

disorders, which would encompass its use for the treatment of tissue as recited by instant claim 2. As such, the agent taught by *Iwase et al* would necessarily inhibit, for example, tissue of the heart as recited by instant claim 2.

12. Instant claims 3-5 are drawn to the agent of claim 1 wherein the excessive effect of NAD(P)H oxidase is caused by diabetes, hypertension, etc (claim 3); cancer or dementia (claim 4); or intake of chemicals (claim 5). Thus, claim 3 further limits the intended use limitation of instant claim 1 by defining the mechanism which produces the excessive effect of NAD(P)H oxidase. Since the prior art structure is identical to the instantly claimed compound structure, this limitation is not afforded patentable weight, as it is asserted that the prior art structure would be capable of inhibiting an excessive effect of NAD(P)H oxidase caused by diabetes, cancer, intake of chemicals, etc as recited by instant claims 3-5. Accordingly, claims 3-5 are rejected. For the same reasons, **claims 9-11**, which are drawn to the agent of *claim 2* wherein the excessive effect of NAD(P)H oxidase (in a tissue of a vascular cell, the heart, the kidney, etc) is caused by diabetes, hypertension, etc (claim 9); cancer or dementia (claim 10); or intake of chemicals (claim 11), are rejected; and **claim 12**, which depends from any of claims 9-11 wherein the compound that does not substantially inhibit the effect of leukocyte NADPH oxidase but inhibits the effect of NAD(P)H oxidase in a tissue other

than leukocyte includes the following compound which encompassed by Applicant's election:  is rejected.

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. **Claims 8 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Iwase et al* (US 5,324,727) in view of *Wu et al* (Mol Endocrinol 16:1590-1597, 2002)**.

16. Claim 8 is drawn to the pharmaceutical composition of claim 7 (and claim 14 is drawn to the composition of claim 13) which is administered simultaneously with a hypolipdemic agent (as elected by Applicant). As discussed above, *Iwase et al* teach the compositions of instant claims 7 and 13. However, Iwase et al do not teach the co-administration with a hypolipidemic agent as recited by instant claims 8 and 14.

17. As stated in MPEP 2144.06, "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626, F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980). As disclosed by *Wu et al*, the hypolipedemic agent guggulsterone also acts as an inhibitor of platelet aggregation (Page 1595, Column 2). Accordingly, it would have been *prima facie* obvious to combine two compositions (the composition taught by *Iwase et al* and guggulsterone) each of which is taught by the prior art to be useful for the same purpose (inhibition of platelet aggregation) to form a third composition to be used for the very same purpose. As such, claims 8 and 14 are rejected as *prima facie* obvious.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CRAIG RICCI whose telephone number is (571) 270-5864. The examiner can normally be reached on Monday through Thursday, and every other Friday, 7:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/CRAIG RICCI/
Examiner, Art Unit 1614

/Ardin Marschel/
Supervisory Patent Examiner, Art Unit 1614